Digitally signed by Poiata Vitalie
Date: 2020.02.19 13:09:57 EET
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA

# LICENȚĂ

**Seria A MMII** **Nr.** 044322

| | |
|---|---|
| Denumirea autorității de licențiere | **Camera de Licențiere** |
| Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență | **Societatea cu Răspundere Limitată "BIOSISTEM MLD"** mun.Chișinău, str. Albișoara, 16/1, ap. 7 |
| Data și numărul certificatului de înregistrare de stat a titularului de licență | 12.08.2010 MD 0101250 |
| Numărul de înregistrare a întreprinderii sau IDNO | 1010600028048 |
| Codul fiscal | |
| Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența | *** Importul, comercializarea, asistența tehnică și reparația dispozitivelor medicale *** |
| Data eliberării licenței | 4 octombrie 2010 |
| Reperfectată: 1)19.10.2012; 2)14.05.2014 | |
| Valabilă pînă la | 4 octombrie 2015 |
| Prelungită pînă la: 03.10.2020 | |

**Semnătura conducătorului autorității de licențiere**

**Director al Camerei de Licențiere**

**Valentin GUZNAC**

L.Ș.

Notă: Licența este valabilă numai cu anexa autentificată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.

# BC "MOLDINDCONBANK" S.A.
# Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000002251429243**.

Codul băncii MOLDMD2X329.

**Director** **Nina Țurcan**

**Director financiar** **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

**Societatea cu Răspundere Limitată "BIOSISTEM MLD"**
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

*Numărul de identificare de stat - codul fiscal*
**1010600028048**

*Data înregistrării* **12.08.2010**

*Data eliberării* **12.08.2010**

**Svirepova Ludmila, registrator**

*Funcția, numele, prenumele persoanei care a eliberat certificatul*

*semnătura*

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

**„CAMERA ÎNREGISTRĂRII DE STAT" Î.S.**
**Secția fonduri speciale și informații curente**

# EXTRAS
## din Registrul de stat al persoanelor juridice

nr. **14419** din **11.07.2016**

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**
Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat și codul fiscal: **1010600028048.**
Data înregistrării de stat: **12.08.2010.**
Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
**1 Activitatea farmaceutică;**
**2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
**3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
**4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
**5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
**6 Consultații în domeniul sistemelor de calcul.**
Capitalul social: **5400** lei.
**Administrator: POIATA VITALIE, IDNP 0983103892591,**
Asociați:
**1. POIATA VITALIE , IDNP 0983103892591**
**cota 1803.60 lei, ce constituie 33,4 %**
**2. NASEDCHIN ALEXANDR , IDNP 2002001070747**
**cota 1798.20 lei, ce constituie 33,3 %**
**3. KOJEVNIKOV DMITRII , IDNP 0972305012362**
**cota 1798.20 lei, ce constituie 33,3 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 11.07.2016.

Specialist principal **Lazari Aliona**
tel. 022-266-252

A A 7 * E A * 0 3 7 0 4 3 1 E A

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

# Lista fondatorilor Biosistem-mld SRL

| Nr. | Nume, Prenume | IDNP |
|---|---|---|
| 1. | Vitalie Poiata | 0983103892591 |
| 2. | Alexandru Nasedchin | 2002001070747 |
| 3. | Dmitrii Kojevnikov | 0972305012362 |

**Anexa nr.7.2 la Instrucţiunea**
**aprobată prin ordinul IFPS**
**nr. 400 din 14 martie 2014**

CC 04 AE

# CERTIFICAT
## privind lipsa sau existenţa restanţelor faţă de bugetul public naţional

**Nr.** / **№** A2003771 **din** / **от** 13.02.2020

**1. Destinaţia** / Назначение

Pentru participarea la proceduri de achizitii publice

**2. Date despre contribuabil** / Информация о налогоплательщике

| **Denumirea** / Наименование | **Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер |
|---|---|
| **BIOSISTEM MLD S.R.L.** | 1010600028048 |
| **Adresa sediului de bază (strada, numărul)** / Адрес основного месторасположения (улица, номер) | **Codul - Denumirea localităţii** / Код - Наименование населенного пункта |
| Albisoara nr.16 bl.1 of.7 | 0150-SEC.RISCANI |

**3. Atestarea lipsei sau existenţei restanţelor conform datelor Sistemului Informaţional Automatizat** / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanţa faţă de bugetul public naţional constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

**4. Valabil pînă la** / Действителен до 28.02.2020

**5. Autentificarea Serviciului Fiscal de Stat** / Подтверждение Государственной налоговой службы

**Şef DDF Rîşcani**
**a DGAF mun.Chişinău**
Funcţia/Должность

Semnătura/Подпись

**Ana STOICOV**
Numele şi prenumele/Фамилия и имя

L.Ş/ М П

Executor: **Claudia GOJAN**
Numele şi prenumele/Фамилия и имя

MINISTERUL FINANȚELOR AL REPUBLICII MOLDOVA
SERVICIUL FISCAL DE STAT
IDNO 1006601001182

Este extras din Sistemul Informaţional al SFS SIA „Contul curent al contribuabilului"// 13.02.2020 ora 11:49:52 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (1,34)

BioSystems
REAGENTS & INSTRUMENTS

# EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

***Hereby DECLARES***

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

**Directive on in Vitro Diagnostic Medical Devices (98/79/EC)**

under the specifications declared by BioSystems S.A.

It means that the products:

- complies with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- is classified as Other Device (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6th, 2012

BioSystems
Costa Brava, 30
08030 BCN

Dr. Antonio Elduque
Managing director
BioSystems S.A.

www.tuv.com ID:9091006696
TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Biosystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
biosystems@biosystems.es
www.biosystems.es

## *CLINICAL CHEMISTRY – BIOCHEMISTRY:*

a-Amylase-Direct
a-Amylase-EPS
a-Amylase-Pancreatic
Acid Phosphatase (ACP)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
AspartateAminotranferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total and direct)
Bilirubin (total)
Calcium – Arsenazo
Calcium – MTB
Cholesterol
Cholesterol HDL
Cholesterol HDL direct
Cholesterol HDL Precipitating reagent
Cholesterol LDL direct
Cholesterol LDL Precipitating reagent
Cholinesterase (CHE)
Citrate
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
Fructosamine
Fructose
g-Glutamyltransferase (g-GT)
Glucose
Iron – Chromazurol
Iron – Ferrozine
Iron Binding Capacity
Lactate Dehydrogenase (LDH)
Lactate Dehydrogenase (LDH) – IFCC
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Pyridoxal Phosphate
Triglycerides
Urea/BUN-Color
Urea/BUN-UV
Uric Acid

## *CLINICAL CHEMISTRY – TURBIDIMETRY:*

a1-acid Glycoprotein
Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Apolipoprotein A-I (Apo A-I)
Apolipoprotein B (Apo B)
b2-Microglobulin
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Prealbumin
Rheumatoid Factors (RF)
Transferrin

## *CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:*

17-Hydroxycorticosteroids
17-Ketosteroids
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)
5-Hydroxyindoleacetic acid (5-HIAA)
Hemoglobin A1C
Hemoglobin A2
Metanephrines
Vanilmandelic Acid

## *CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:*

a-1-acid Glycoprotein Standard
Adenosine Deaminase (ADA) Standard
Albumin (Microalbuminuria) Standard
Anti-Streptolysin O (ASO) Standard
Antithrombin III Standard
Apolipoprotein A-I Standard
Apolipoprotein B Standard
b2-Microglobulin Standard
Bilirubin Standard
Biochemistry Calibrator
Biochemistry Calibrator (Human)
Cholesterol HDL/LDL Calibrator
CRP/CRP-hs Standard
Ferritin Standard
Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard
Prealbumin Standard
Protein Calibrators
Protein (urine) Standard
Rheumatoid Factors (RF) Standard

## *CLINICAL CHEMISTRY – INSTRUMENTS:*

A15
A25
BA400
BTS-350

## *CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:*

a-Amylase-Direct
a-Amylase-Pancreatic
Adenosine Deaminase (ADA)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
Aspartate Aminotransferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total)
Calcium-Arsenazo
Cholesterol
Cholesterol HDL direct
Cholesterol LDL direct
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
g-Glutamyltransferase (g-GT)
Glucose
Iron Ferrozine
Lactate dehydrogenase (LDH)
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Triglycerides
Urea/BUN UV
Uric acid

## *CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:*

Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Hemoglobin A1C-Turbi (HbA1C-Turbi)
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Rheumatoid Factors (RF)
Transferrin

## *CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:*

ADA Controls
Biochemistry Control Serum (Human) I
Biochemistry Control Serum (Human) II
Biochemistry Control Serum I
Biochemistry Control Serum II
CK-MB Control Serum
Control Urine
Fertility Biochemistry Control
Hemoglobin A1C Control (Elevated)
Hemoglobin A1C Control (Normal)
Hemoglobin A2 Control
Lipid Control Serum I
Lipid Control Serum II
Protein Control Serum I
Protein Control Serum II
Rheumatoid Control Serum I
Rheumatoid Control Serum II

## *AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):*

Anti-Adrenal Cortex Antibodies (AACA)
Anti-Endomysium Antibodies (AEA)
Anti-Islet Cell Antibodies (AICA)
Anti-Keratin Antibodies (AKA)
Anti-Mitochondrial Antibodies (AMA)
Anti-nDNA antibodies (nDNA)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)
Anti-Nuclear Antibodies RL (ANA-RL)
Anti-Skin Antibodies (ASA)
Anti-Smooth Muscle Antibodies (ASMA)
Anti-Striated Muscle Antibodies (AStMA)
Anti-Thyroid Antibodies (ATA)
Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Autoantibodies MsK/MsS (AA-MsK/MsS)
Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Autoantibodies RK/RS (AA-RK/RS)
Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Glomerular Basement Membrane Antibodies (GBMA)

## *AUTOIMMUNITY – ELISA:*

ANA Screening
Anti-Annexin V IgG/IgM (ANX)
Anti-b2-Glycoprotein 1 IgG/IgM (b2GP1)
Anti-Cardiolipin Antibodies (ACA-IgG/IgM)
Anti-Centromere B Antibodies (CENP-B)
Anti-Citrullinated Protein Antibodies (ACPA)
Anti-Deamidated Gliadin Peptides IgA (DGP IgA)
Anti-Deamidated Gliadin Peptides IgG (DGP IgG)
Anti-dsDNA Antibodies
Anti-GBM Antibodies - EIA (GBM)
Anti-Gliadin Antibodies (AGA-IgG/IgA)
Anti-Histones Antibodies (HIST)
Anti-Insulin Antibodies (INS)
Anti-Jo1 Antibodies
Anti-M2 Antibodies (M2)
Anti-MPO Antibodies
Anti-Nucleosome Antibodies (NCL)
Anti-Phospholipid IgG/IgM (APLA)
Anti-PR3 Antibodies
Anti-Ribosomal P Antibodies (Rib P)
Anti-Scl70 Antibodies
Anti-Sm Antibodies
Anti-Sm/RNP Antibodies
Anti-SSA (Ro) Antibodies
Anti-SSB (La) Antibodies
Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Thyroid Peroxidase Antibodies (Anti-TPO)
Anti-tTransglutaminase IgA Antibodies (Anti- tTG IgA)
Anti-tTransglutaminase IgG Antibodies (Anti- tTG IgG)
ASCA-IgG/IgA (ASCA)
ENA 4-Profile
ENA 6-Screening

## *AUTOINMUNIDAD – INSTRUMENTOS:*
## *AUTOIMMUNITY – INSTRUMENTS:*

iPRO

## *RAPID TESTS – LATEX AGGLUTINATION:*

Anti-Streptolysin O (ASO) - Slide
C-Reactive Protein (CRP) - Slide
Rheumatoid factors (RF) - Slide

## *INFECTIOUS IMMUNOLOGY – SYPHILIS:*

RPR-Carbon
TPHA

## *INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:*

Febrile Serodiagnostics Multiscreening
Febrile Serodiagnostics Salmonella
Brucella abortus
Brucella abortus, Rose Bengal
Proteus Ox19
Salmonella paratyphi AH
Salmonella paratyphi AO
Salmonella paratyphi BH
Salmonella paratyphi BO
Salmonella paratyphi CH
Salmonella paratyphi CO
Salmonella typhi H
Salmonella typhi O
Brucella Positive Control
Proteus Positive Control
Salmonella Positive Control
Serology Negative Control

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 6696

Certificate Holder: **BIOSYSTEMS S.A.**
Costa Brava, 30
08030 Barcelona
Spain

(including the locations according to annex)

Scope: Design, development, manufacture, distribution, installation and servicing of:
- Instruments and reagents for clinical diagnostic.
- Instruments and reagents for agro-alimentary analysis.
Distribution and servicing of instruments and reagents for veterinary diagnosis.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2017-12-13 until 2019-12-18.
First certification 1996

2017-12-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 6696

| No. | Location | Scope |
|---|---|---|
| /01 | **BIOSYSTEMS, S.A.**<br>Pl. Can Tapioles naus 7-12-13<br>08110 Montcada i Reixac<br>Spain | Labelling and assembling of reagents.<br>Warehousing and shipment of:<br>-Instruments and Reagents for clinical diagnostic.<br>-Instruments and Reagents for agro-alimentary analysis.<br>-Instruments and Reagents for veterinary diagnosis. |

2017-12-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

TÜVRheinland®

# Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**BIOSYSTEMS S.A.**
**Costa Brava 30**
**08030 Barcelona**
**Spain**

has established and applies a quality management system for medical devices for the following scope:

**Design and development, manufacture, distribution and servicing of instruments and reagents for clinical diagnostic**
**(see attachment for sites included)**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

| | |
|---|---|
| Effective Date: | 2017-11-28 |
| Certificate Registration No.: | SX 60124804 0001 |
| An audit was performed. Report No.: | 28300434 002 |
| This Certificate is valid until: | 2019-12-12 |

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2017-11-28

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

X. Ren

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to Certificate**
**Registration No.:** SX 60124804 0001
**Report No.:** 28300434 002

**Organization:**
BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

**Scope:**

Site included:
Polígono Industrial "Can Tapioles"
Naves 7, 12 y 13
08110 Montcada i Reixac (Barcelona)
Spain

Scope:
Labelling and Assembling of reagents and Warehousing and Shipment of instruments and reagents for clinical diagnostic

**Certification Body**

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

**Date:** 2017-11-28

X. Ren

CE

# EC DECLARATION OF CONFORMITY

Apacor Limited declares that the devices listed below conform to the relevant provisions of the EC Council Directive In Vitro Diagnostic Devices Directive 98/79/EC dated 27 October 1998. This compliance has been properly documented using checklist created from Annex III excluding point 6 of the Directive, linked to all supporting Technical Documentation.

Apacor Limited has a Quality Management System in place, which complies with ISO 13485 (Certificate Number GB18/873854) regulations and agrees to develop, implement and maintain the Quality Management System to ensure continued adequacy and efficacy.

| PRODUCT DESCRIPTION | PRODUCT CODE | EDMS CODE | CATEGORY |
|---|---|---|---|
| MIDI PARASEP | 145000, 145300, 145400, 145500, 145501, 145650, 145750, 249200 | 15051090 | Other Parasitology |
| MIDI PARASEP SF | 149900, 149910, 149920, 149931, 149932, 149650, 149750, 249300 | 15051090 | Other Parasitology |
| MINI PARASEP | 146000, 146200, 146300, 146400, 146500, 146501, 146650, 146750, 248200 | 15051090 | Other Parasitology |
| MINI PARASEP SF | 148800, 148900, 148910, 148920, 148931, 148932, 148935, 148980, 148650, 148750, 248930,108000,180880, 108810,108900,108910,108920,108931, 108932,108935 | 15051090 | Other Parasitology |
| MAXI PARASEP | 147001 | 15051090 | Other Parasitology |
| 30ML TRANSPORT VIALS | 148998, 249400, 249420 | 15051090 | Other Parasitology |
| CLEAN VIAL | 149970 | 15051090 | Other Parasitology |

This Declaration of Conformity is signed below, certifying these requirements have been met.

Janet MacKenzie
General Manager
15 September 2018

Apacor Limited, Unit 5 Sapphire Centre, Fishponds Road, Wokingham, RG41 2QL, England

CE

# EC DECLARATION OF CONFORMITY

## MINI PARASEP SF FAECAL CONCENTRATOR

Apacor Ltd declares that the devices listed below conform to the relevant provisions of the EC Council Directive In Vitro Diagnostic Devices Directive 98/79/EC dated 27 October 1998. This compliance has been properly documented using checklist created from Annex III excluding point 6 of the Directive, linked to all supporting Technical Documentation.

MINI PARASEP SF CONCENTRATOR (148900)
Category: Other/General Device
CE Classification # 15051090

Apacor Ltd has a Quality System in place, which complies with ISO 9001 - 2008 regulations and agrees to develop, implement and maintain the Quality Management System to ensure continued adequacy and efficacy. Certificate Number GB96/8685.

This Declaration of Conformity is signed below, certifying these requirements have been met.

Janet MacKenzie
**General Manager – Apacor Limited**

3rd September 2014

Apacor Ltd, Unit 5, The Sapphire Centre, Fishponds Rd, Wokingham, RG41 2QL, England

CE

# EC DECLARATION OF CONFORMITY

## WORKSTATIONS

Apacor Ltd declares that the devices listed below conform to the relevant provisions of the EC Council Directive In Vitro Diagnostic Devices Directive 98/79/EC dated 27 October 1998, the Low-Voltage Directive 2006/95/CE, also comply with the requirements of EMC Directive 2004/108/CE, tested to standards EN 61326-2-4:2006; EN 61000-4-2:2009; EN 61000-4-3:2006 CISPR 22:2008 Class B. This compliance has been properly documented using checklist created from Annex III excluding point 6 of the Directive, linked to all supporting Technical Documentation.

PARASYS (170000)
Category: Other/General Device
CE Classification # 28011001

Apacor Ltd has a Quality System in place, which complies with ISO 9001 - 2008 regulations and agrees to develop, implement and maintain the Quality Management System to ensure continued adequacy and efficacy.
Certificate Number GB96/8685.

This Declaration of Conformity is signed below, certifying these requirements have been met.

Janet MacKenzie
**General Manager –Apacor Limited**

3rd September 2014

Apacor Ltd, Unit 5, The Sapphire Centre, Fishponds Rd, Wokingham, RG41 2QL, England

# Declaration of Conformity CE

**Manufacturer:** Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

**Product:** **Auto Hematology Analyzer**
**Model:** **BC-3600**
Including reagents as following:
**M-30D DILUENT**
**M-30CFL LYSE**
**M-30R RINSE**
**PROBE CLEANSER**



**Classification:** The device not in IVDD annex II and not for self testing/performance evaluation

**Conformity Assessment Route:** IVDD Annex III(excluding Section 6)

**We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.**

## Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

**Start of CE-Marking:** 2011-01-14
**Place, Date of Issue:** Shenzhen, 2011-01-14

**Signature:** .....
**Name of Authorized Signatory:** Mr. Yang Long
**Position Held in Company:** Management Representative

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

# CERTIFICATE

**No. Q5 17 03 44751 089**

**Holder of Certificate:** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

**Scope of Certificate:**

**Design and development,
production and distribution of
Active medical devices (intended) for monitoring,
diagnosis, anesthesia, breathing and intensive care;
In-vitro diagnostic instruments;
Non-active accessories
for breathing therapy and anesthesia;
In-vitro diagnostic reagents and kits (intended)
for hematology, clinical chemistry,
immunology and cell analysis
(For detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1705528

**Valid from:** 2017-09-01
**Valid until:** 2020-08-31

0405276870507S

**Date,** 2017-06-28

Stefan Preiß



DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00



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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

# CERTIFICATE
# No. Q5 17 03 44751 089

**Applied Standard(s):**

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

**Facility(ies):**

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Bldg 9-13, Baiwangxin High-Tech Industrial Park, Baimang, Xili Town, Nanshan, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

**Shenzhen Mindray Biomedical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**



DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00



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Product Service

**Attachment for Certificate No. Q5 17 03 44751 089**
**Dated: 2017-06-28**

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder,
Anesthesia Machine and Accessories, Ventilator,
Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System,
Ultrasonic Diagnostic Equipment and Accessories,
Digital Radiography System, Radiography System, Magnetic Resonance Imaging System
Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader,
Microplate Washer for invitro diagnostic use, Chemiluminescence Immunossay Analyzer,
Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer,
Glycohemoglobin Analyzer, Specific Protein Analyzer,
Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer,
Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer,
Calibrators and Controls for Glycohemoglobin Analyzer,
Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask,
Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger,
Filter, Breathing Bag

Munich, CRT, 2017-06-28

Stefan Preiß



DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00



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America

# CERTIFICATE

## No. QS5 17 07 44751 097

**Certificate Holder:**

Shenzhen Mindray Bio-Medical
Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

TÜV SÜD ISO 9001

**Scope of Certificate:**

Design and Development, Production and Distribution of Medical Electronic Equipment (Including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger,

**Standard(s):** ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

**Report No.:** M2606
**Effective Date:** 2017-07-01
**Expiry Date:** 2020-06-30

Earl Buckmiller
Director, Quality Systems & MS Cert. Body

040527682186 43



TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®

SCC Accredited CB-MS OCSM Accrédité CCN

UCB_F_12.04 2012-02

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America

# CERTIFICATE

## No. QS5 17 07 44751 097

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
**Mindray Building**
**Keji 12th Road South**
**High-Tech Industrial Park**
**Nanshan, 518057 Shenzhen**
**PEOPLE'S REPUBLIC OF CHINA**

**Design and Development, Production and Distribution of Medical Electronic Equipment (Including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag**

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
**Bldg 9-13, Baiwangxin High-Tech Industrial Park**
**Baimang, Xili Town**
**Nanshan, 518108 Shenzhen**
**PEOPLE'S REPUBLIC OF CHINA**

**Design and Development, Manufacturing of Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine, Ventilator, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System. Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag**

**Effective Date:** **2017-07-01**
**Expiry Date:** **2020-06-30**

Earl Buckmiller
Director, Quality Systems & MS Cert. Body



TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®

SCC Accredited CB-MS OCSM Accrédité CCN

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America

# CERTIFICATE

## No. QS5 17 07 44751 097

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
**1203 Nanhuan Avenue**
**Guangming District**
**518016 Shenzhen**
**PEOPLE'S REPUBLIC OF CHINA**

**Design and Development, Production and Distribution of Medical Electronic Equipment (Including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor , Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories (Ultrasonic Transducer), Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag**

**Effective Date:** **2017-07-01**
**Expiry Date:** **2020-06-30**

Earl Buckmiller
Director, Quality Systems & MS Cert. Body



TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

SCC Accredited CB-MS OCSM Accrédité CCN

# CERTIFICATE

**No. J - 2670/2/2018**

**This is to certify that:**

## TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.

## Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5 35621 Çiğli, İzmir, Turkey

## Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey

**is in conformance with**

## EN ISO 9001:2015

**in the following scope of activities:**

## design, development, manufacturing, final control and distribution of in vitro diagnostic medical devices intended for self-testing and professional use, ECG electrodes and antibiotic susceptibility discs

**The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.**

**This Certificate shall remain valid provided that above standard are respected by the Organization.**

**This certificate is valid:**

**from 24.08.2018 to 21.12.2020**

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania

AC 019
QMS

IAF Member of Multilateral Recognition Arrangement

Anna Wyroba, M.Sc.
Vice President


Certificate No. **J - 2670/2/2018**
Issued under the Contract No. 2897/JM/3/2017
Date of certification decision: 24.08.2018
Bears the PCBC hologram.
Warsaw, 24.08.2018

TÜRKLAB
let us diagnose

FACTORY
ITOB 10031 Sk. No:15 Menderes – Izmir / TURKEY
www.turklab.com.tr

HEAD OFFICE
Sasali Merkez Mah. Doğa Dostları Sitesi 131. Sok. No:2/5 Çiğli - İzmir
Tel: +90 232 376 80 81 Fax: +90 232 376 80 40

21.08.2016
Izmir / Turkey

## DECLARATION FOR THE ISSUANCE OF QUALITY CERTIFICATES

To Whom It May Concern,

According to IVD 98/79/EC directive,

FOR ANNEX II LIST A which includes HIV, Hepatitis B and Hepatitis C tests; the Notified Body must verify that the product meets the Common Technical Specification (CTS) and must release each batch of product before it is placed on the European market. The batch release often requires testing. These have EC Design Examination certificates by the notified body.

FOR ANNEX III which includes all other tests for Professional use; the manufacturer prepares a declaration of conformity in a similar way to the general devices.

For the above mentioned reason, we hereby declare that we provide CE Certificate for only the Hepatitis B, Hepatitis C and HIV tests for Professional use. For the group of other Professional tests; it is enough to present a self-Declaration of Conformity to the EU standards.

Cordially,

TURKLAB TIBBİ MALZEMELER SAN TİC A.Ş



# POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

## EC CERTIFICATE No. 1434-IVDD-56/2016

**EC Design-Examination**

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

**HBsAg Test**
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**
**ITOB 10031 Sokak No: 15 Tekeli Menderes**
**Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

**Anna Wyroba**
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 45/2016
Contract No. MD-18/2016

Module H6

# POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

## EC CERTIFICATE No. 1434-IVDD-57/2016

**Full Quality Assurance System**

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**
**ITOB 10031 Sokak No: 15 Tekeli Menderes**
**Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices, List A:

**HBsAg Test**
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. 4, 6 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law. The audit of the quality assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

**Anna Wyroba**
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 45/2016
Contract No. MD-18/2016

Module H7


# POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION


## EC CERTIFICATE No. 1434-IVDD-52/2016

**EC Design-Examination**

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

**Anti-HCV Test**
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**
**ITOB 10031 Sokak No: 15 Tekeli Menderes**
**Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

**Anna Wyroba**
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 43/2016
Contract No. MD-16/2016

Module H6

# POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

## EC CERTIFICATE No. 1434-IVDD-53/2016

**Full Quality Assurance System**

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**
**ITOB 10031 Sokak No: 15 Tekeli Menderes**
**Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices, List A:

**Anti-HCV Test**
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law. The audit of the quality assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

**Anna Wyroba**
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 43/2016
Contract No. MD-16/2016

Module H7


# POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION


## EC CERTIFICATE No. 1434-IVDD-54/2016

**EC Design-Examination**

**Directive 98/79/ECon in vitro diagnostic medical devices**

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

**Anti-HBs Test**
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**
**ITOB 10031 Sokak No: 15 Tekeli Menderes**
**Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

**Anna Wyroba**
Vice President of PCBC

CE 1434


PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw


Application No. 44/2016
Contract No. MD-17/2016

Module H6

# POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

## EC CERTIFICATE No. 1434-IVDD-55/2016

**Full Quality Assurance System**

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**
**ITOB 10031 Sokak No: 15 Tekeli Menderes**
**Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices, List A:

**Anti-HBs Test**
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law. The audit of the quality assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

**Anna Wyroba**
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 44/2016
Contract No. MD-17/2016

Module H7


# POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION


## EC CERTIFICATE No. 1434-IVDD-58/2016

**EC Design-Examination**

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

**Anti - HIV 1/2 Test**
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**
**ITOB 10031 Sokak No: 15 Tekeli Menderes**
**Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

**Anna Wyroba**
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 46/2016
Contract No. MD-19/2016

Module H6

# POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

## EC CERTIFICATE No. 1434-IVDD-59/2016

**Full Quality Assurance System**

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**
**ITOB 10031 Sokak No: 15 Tekeli Menderes**
**Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices,
List A:

**Anti - HIV 1/2 Test**
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law. The audit of the quality assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

**Anna Wyroba**
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 46/2016
Contract No. MD-19/2016

Module H7


# POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION


## EC CERTIFICATE No. 1434-IVDD-51/2016

**EC Design-Examination**

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies that the design documentation relating to in vitro diagnostic medical device for self-testing:

**hCG Pregnancy Test**
**Brands: Rapidan Nova®, Rapidan Optima®, Info®, Toyo®, Rapidan Tester®, Rapidan Compact®, Labmen®**

manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**
**ITOB 10031 Sokak No: 15 Tekeli Menderes**
**Izmir, Turkey**

was examined by PCBC according to Annex III p. 6 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

**Anna Wyroba**
Vice President of PCBC

CE 1434


PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw


Application No. 42/2016
Contract No. MD-15/2016

Module A1

# CERTIFICATE

**No. M - 56/2/2018**

**This is to certify that:**

## TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.

## Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5 35621 Çiğli, İzmir, Turkey

## Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey

**is in conformance with**

## EN ISO 13485:2016

**in the following scope of activities:**

## design, development, manufacturing, final control and distribution of in vitro diagnostic medical devices intended for self-testing and professional use, ECG electrodes and antibiotic susceptibility discs

**The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.**

**This Certificate shall remain valid provided that above standard are respected by the Organization.**

**This certificate is valid:**

**from 24.08.2018 to 21.12.2020**

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania

AC 019
QMS

IAF Member of Multilateral Recognition Arrangement

Anna Wyroba, M.Sc.
Vice President


Certificate No. **M - 56/2/2018**
Issued under the Contract No. 2897/JM/3/2017
Date of certification decision: 24.08.2018
Bears the PCBC hologram.
Warsaw, 24.08.2018